Sheet 1 of 4

EXPRESS MAIL NO: EV 159435376 US: 869-BAZ-US APPLICATION NO 8002-081-999 To be assigned LIST OF REFERENCES CITED BY APPLICANT APPLICANT Pawelek et al. (Use several sheets if necessary) FILING DATE GROUP 1636 Concurrently herewith U.S. PATENT DOCUMENTS FILING DATE *EXAMINER DOCUMENT NUMBER DATE NAME CLASS SUBCLASS IF APPROPRIATE INITIAL 03/13/84 Ribi A01 4,436,727 A02 5,021,234 06/04/91 Ehrenfeld A03 5,344,762 09/06/94 Karapetian A04 5,830,702 11/03/98 Portnoy et al. A05 6,051,237 04/18/02 Paterson FOREIGN PATENT DOCUMENTS DOCUMENT NUMBER COUNTRY CLASS SUBCLASS TRANSLATION DATE **B01** WO 92/11361 7-9-92 PCT WO 95/02048 1-19-95 PCT B02 WO 96/11277 4-18-96 PCT **B03** 3/10/1993 B04 0 564 121 A2 EPO (Ref. No. 1 of Japanese Office Action) Japan (Ref. No. 2 of Japanese 6/29/1987 62145026 A B05 Office Action) Japan (Ref. No. 3 of Japanese 10/25/1994 06298657A B06 Office Action) 7/18/1989 Japan (Ref. No. 4 of Japanese 01180830 A **B07** Office Action) 6/05/1988 Japan (Ref. No. 5 of Japanese 63101328 A **B08** Office Action) PCT (counterpart of 6-505158) WO 92/15689 9/17/1992 **B09** (Ref. No. 6 of Japanese Office Action) 3/02/1995 PCT (Ref. No. 7 of Japanese WO 95/05835 **B10** Office Action) OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.) Tsujitani, S. et al., 1998 Cancer 61: 1749-1753 Endoscopic Intratumoral Injection of OK-432 and Langerhans' Cells in C01 Patients With Gastric Carcinoma Okamoto M. et al., 2002 Anticancer Res. 22: 3229-40 Enhancement of Anti-tumor Immunity by Lipteichoic Acid-C02 related Molecule Isolated from OK-432, a Streptococcal Agent, in Athymic Nude Mice Bearing Human Salivary Adenocarcinoma: Role of Natural Killer Cells Hohmann et al., 1995, PNAS 92(7): 2904-08 Macrophage-inducible expression of a model antigen in Salmonella typhimurium enhances immunogenicity J. Adler, 1973, "A method of measuring chemotaxis and use of the method to determine optimum conditions C04 for chemotaxis by Escherichia coli", J Gen Microbiol 74:77-91. Alizadeh et al., 1994, "Apoptosis as a mechanism of cytosis of tumor cells by a pathogenic free-living C05 amoeba", Infect Immun 62:1298-1303. K. Bagshawe, 1995, "Antibody-directed enzyme prodrug therapy: A review", Drug Dev Res 34:220-230. C06 Barry et al., 1995, "Protection against mycoplasma using expression library immunization", Nature C07 377:632-635.

Barth and Morton, 1995, "The role of adjuvant therapy in melanoma management", Cancer 75

NY2: 1482992.1

Jennit Dunst

(Suppl.2):726-734.

C08

7/29/2005

SEST AVAILABLE COPY

Sheet 2 01 4

EXPRESS MAIL NO: EV 159435376 US:

		EXPRESS MAIL NO: EV 159435376 US:
ap	C09	R. Berggren, 1995, "Recombinant salmonella as an oral HIV vaccine", NIH project number 5 K01 Al01248-02.
ab	C10	R. Bone, 1993, "Gram-negative sepsis: A dilemma of modern medicine", Clin Microbiol Rev 6:57-68.
	C11	Bonnekoh et al., 1995, "Inhibition of melanoma growth by adenoviral-mediated HSV thymidine kinase gene transfer in vivo", J Invest Derm 104:313-317.
90 90	C12	Carey et al., "Clostridial oncolysis in man", Eur. J. Cancer 3:37-46
90	C13	Carrier et al, 1996, "Expression of human IL-1ÿ in Salmonella typhimurium; a model system for the delivery of recombinant therapeutic proteins in vivo", J. Immunology 148:1176-1181
90	C14	Carswell et al., 1975, "An endotoxin-induced serum factor that causes necrosis of tumors", <u>Proc Natl Acad Sci</u> 72:3666-3669.
	C15	Chabalgoity et al., 1996, "A Salmonella typhimurium htrA live vaccine expressing multiple copies of a
90		peptide comprising amino acids 8-23 of herpes simplex virus glycoprotein D as a genetic fusion to tetanus
	C16	toxin fragment C protects mice from herpes simplex virus infection", Microbiol. 19:791-801 Christ et al., 1995, "E5531, a pure endotoxin antagonist of high potency", Science 268:80-83.
90		J. Clements, 1995, "Attenuated salmonella as vaccine vectors", NIH project number 5 R01 Al 28835-06.
3	C18	Cunningham et al., 1992, "Actin-binding protein requirement for cortical stability and efficient locomotion",
20	C19	Science 255:325-327. R. Curtiss, 1995, "Biological containment of live bacterial vaccines", NIH project number 1 R41 Al38599-01.
90	I .	R. Curtiss, 1994, "Avirulent salmonella host-vector vaccine systems", NIH project number 1 R41
90	C21	Al36585-01. E. Eidenstadt, 1987, "Analysis of mutagenesis", from Escherichia coli and Salmonella typhimurium, Cellular
90		and Molecular Biology, Neidhardt et al. (ed.), pp. 1016-1033.
90	C22	Cancer Research 24:239-243
002		S. Falkow, 1991, "Bacterial entry into eukaryotie cells", Cell 65:1099-1102. Duplicate (gaf
90		Fox, et al., 1996, "Anaerobic bacteria as a delivery system for cancer gene therapy: in vitro activation of 5-fluorocytosine by genetically engineered Clostndia", Gene Therapy 3:173-178
90		S. Friberg, 1993, "BCG in the treatment of superficial cancer of the bladder: A review", Med Oncol Tumor Pharmacother 10:31-36.
00	C26	J. Galan, 1995, "Novel salmonella antigen delivery vectors", NIH project number 5 R01 Al36520-02.
	C27	Gericke and Engelbart, 1963, "Oncolysis by Clostridia. II. Experiments on a tumor spectrum with a variety of Clostridia in combination with heavy metal", Cancer Research 24:217-221
80		P. Gulig, 1994, "Salmonella typhimurium virulence plasmid", NIH project number 5 R29 Al28421-05.
9D		Hall et al., 1994, "Induced regression of bovine papillomas by intralesional immunotherapy", Therapeutic Immunol. 1:319-324
30		Han et al., 1967, "Salmonellosis in disseminated malignant diseases", New Eng J Med 276(11):1045-1052.
AD	 	R. Jain, 1994, "Barriers to Drug Delivery in Solid Tumors", Scientific American 7:58-65.
90	C32	Infect Immun 60:2475-2480.
90	C33	multicopy suppresssor of Null mutations in the high-temperature requirement gene htrB", J. Bacteriology 174:702-710
QD.	C34	Klimpel et al., 1990, "Bacteria-infected fibroblasts have enhanced susceptibility to the cytotoxic action of tumor necrosis factor", J Immunol 145:711-717.
90 90 90	C35	Lee et al., 1992, "Identification of a Salmonella typhimurium invasion locus by selection for hyperinvasive mutants", Proc Natl Acad Sci 89:1847-1851.
ap	C36	Lemmon et al., 1994, "Anaerobic bacteria as a gene delivery system to tumors", Proc. Am. Assn. Cancer Research 35:374 (Abstract 2231)
ap	C37	
90	C38	Loppnow et al., 1990, "Cytokine induction by lipopolysaccharide (LPS) corresponds to lethal toxicity and is inhibited by nontoxic <i>Rhodobacter capsulatus</i> LPS", Infect Immun 58:3743-3750.
90	C39	
90	C40	R. Macnab, 1992, "Genetics and biogenesis of bacterial flagella", Ann Rev Genet 26:131-158.
90	C41	Science 259:686-688.
90	C42	

NY2: 1482992.1

Jennif Denor

7/29/2005

BEST AVAILABLE COPY

Sheet 3 of 4

		EXPRESS MAIL NO: EV 159435376 US:
SD.	C43	number 5 R01 DE09081-05.
Ø₽	C44	Miller et al., 1969, A two-component regulatory system (phor-phy) controls Salmonella typnimunum
<u>0</u>	C45	virulence", Proc Natl Acad Sci 86:5054-5058. V. Miller, 1995, "Entry into eukaryotic cells by salmonella and yersinia", NIH project number 5 K04
20	C46	
9D 9D	C47	phenotype in Salmonellae", Infect Immun 60:3763-3770. Minton et al, 1995, "Chemotherapeutic tumour targeting using Clostridial spores", FEMS Micro. Rev. 17:357-364
90	C48 I	Möse and Möse, 1963, "Oncolysis by Clostridia. I. Activity of Clostidium butyricum (M-55) and other nonpathogenic Clostridia against the Ehrlich carcinoma", Cancer Research 24:212-216
90		Mullen et al., 1992, "Transfer of the bacterial gene for cytosine deaminase to mammalian cells confers lethal sensitivity to 5-fluorocytosine: a negative selection system", PNAS (USA) 89:171-176
90	C50 (Nauts et al., 1953, "A review of the influence of bacterial infection and of bacterial products (Coley's toxins) o malignant tumors in man", Acta Medica Scandinavica 145 (Suppl. 276):1-105.
20		Pan et al., 1995, " A recombinant Listeria Monocytogenes vaccine expressing a model tumour antigen protects mice against lethal tumour cell challenge and causes regression of established tumours", Nature Medicine 1:471-477.
9D		Parker et al., "Effect of histiocyticus infection and toxin on transplantable mouse tumors", 1947, Pro. Soc. Exp Biol. Med. 16124:461-467
9D		Pawelek et al., 1995, "Macrophage characteristics of metastatic melanoma", <u>J Invest Dermatol</u> 104:605 (Abstract 304).
9D	C54 (Pidherney et al., 1993, "In vitro and in vivo tumoricidal properties of a pathogenic free-living amoeba", <u>Cancer</u> <u>Letters</u> 72:91-98.
9P		A. Pugsley, 1988, "Protein secretion across the outer membrane of gram-negative bacteria" In: <u>Protein</u> <u>Transfer and Organelle Biogenesis</u> , Dand and Robbins (eds.), Academic Press, Inc., Harcourt Brace Jovanovich, Publishers, San Diego, pp. 607-652.
90	C56 (Raue and Cashel, 1975, "Regulation of RNA synthesis in <i>Escherichia coli</i> ", Biochimica et Biophysica Acta 383:290-304
AP	C57 (Reinhard et al., 1950, "Chemotherapy of malignant neoplastic diseases", <u>JAMA</u> 142(6):383-390.
90	C58 (Saltzman et al., 1996, "Attenuated Salmonella typhimurium containig interleukin-2 decreases MC-38 hepatic metastases: a novel anti-tumor agent", Cancer Biotherapy and Radiopharmaceuticals 11:145-153
90		Schafer et al., 1992, "Induction of a cellular immune response to a foreign antigen by a recombinant <i>Listeria</i> monocytogenes vaccine", J. Immunnol. 149:53
90	C60 (Schlechte and Elbe, 1988, "Recombinant plasmid DNA variation of <i>Clostridium oncolyticum</i> - model experiments of cancerostatic gene transfer", Zbl. Bakt. Hyg. A 268:347-356
ap	C61 (Schlechte et al., 1982, "Chemotherapy for tumours using Clostridial oncolysis, antibiotics and cyclophosphamide: model trial on the UVT 15264 tumour", Arch. Geschwulstforsch 52:41-48
9D.	C62 (Shaw et al., 1991, "The human dioxin-inducible NAD(P)H: quinone oxidoreductase cDNA-encoded protein expressed in COS-1 cells is identical to diaphorase 4", Eur. J. Biochem. 195:171-176
90		Sizemore et al., 1995, "Attenuated Shigella as a DNA Delivery Vehicle for DNA-Mediated Immunization", Science 270:299-302.
3P	C64 (Slauch et al., 1994, "In vivo expression technology for selection of bacterial genes specifically induced in host tissues", Meth Enzymol 235:481-492.
90	C65 (Somerville et al., "A novel <i>Escherichia coli</i> lipid A mutant that produces an antiinflammatory lipopolysaccharide", J. Clin. Invest. 97:359-365
ap	C66 (Sosnowski et al., 1994, "Complications of bacillus calmette-guerin (BCG) immunotherapy in superficial bladder cancer", Comp Ther 20:695-701.
90		Su et al., 1992, "Extracellular export of Shiga toxin B-subunit/haemolysin A (C-terminus) fusion protein expressed in Salmonella typhimurium aroA-mutant and stimulation of B-subunit specific antibody responses in mice", Microbial Pathogenesis 13:465-476
90	C68 (Takayma et al., 1989, "Diphosphoryl lipid A from Rhodopseudomonas sphaeroides ATCC 17023 blocks induction of cachectin in macrophages by lipopolysaccharide", Infect Immun 57:1336-1338.

NY2: 1482992.1

Jennif Dens 7/29/2005

AVAILABLE CA-

Sheet 4 of 4 EXPRESS MAIL NO: EV 159435376 US:

		2711 10205 171 17 137 43537 0 US.
9	C69	Thiele et al., 1963, "Oncolysis by Clostidia. III. Effects of Clostridia and chemotherapeutic agents on rodent
		tumors", Cancer Research 24:222-232
90		Thiele et al., 1963, "Oncolysis by Clostridia. IV. Effect of nonpathogenic Clostridial spores in normal and pathological tissues", 1963, Cancer Research 24:234-238
90	C71	Tuomanen, 1993, "Subversion of leukocyte adhesion systems by respiratory pathogens", <u>Am Soc Microbiol</u> 59:292-296.
90	C72	Vinopal, 1987, "Selectable phenotypes", from <u>Escherichia coli and Salmonella typhimurium, Cellular and Molecular Biology</u> , Neidhardt et al. (ed.), pp. 990-1015.
90	C73	Wolfe et al., 1971, "Salmonellosis in patients with neoplastic disease", <u>Arch Intern Med</u> 128:547-554.
90	C74	Eisenstein et al., 1995, "Immunotherapy of a plasmacytoma with attenuated salmonella", Medical Oncol. 12(2):103-108.
90	C75	Bast RC Jr et al., "Antitumor activity of bacterial infection. II. effect of Listeria monocytogenes on growth of a guinea pig hepatoma", J Natl Cancer Inst. 1975 Mar;54(3):757-61
gp	C76	Bast RC Jr, "Antitumor activity of bacterial infection. I. Effect of Listeria monocytogenes on growth of a murine fibrosarcoma", J Natl Cancer Inst. 1975 Mar;54(3):749-56.
AP	C77	Hibbs et al., Role of activated macrophages in nonspecific resistance to neoplasia", J Reticuloendothel Soc. 1976 Sep;20(3):223-31
90	C78	Keller R, "Resistance to a non-immunogenic tumor, induced by Corynebacterium parvum or Listeria monocytogenes, is abrogated by anti-interferon gamma", Int J Cancer. 1990 Oct 15;46(4):687-90
90	C79	Koshimura et al., "On the streptolysin S synthetizing and anticancer activities of cell-free extract from living hemolytic streptococci", Cncer Chemo. 13:107
90	C80	Mizutani and Mitsuoka, 1980, "Inhibitory Effect of Some Intestinal Bacteria on Liver Tumorigenesis in Gnotobiotic C3H/He Male Mice," Cancer Letter <u>11</u> :89-96.
90	C81	Murata et al., 1965, "Oncolytic Effect of Proteus Mirabilis Upon Tumor Bearing Animal," Life Science 4:1055-67.
90		North et al., "T-cell-mediated concomitant immunity to syngeneic tumors. I. Activated macrophages as the expressors of nonspecific immunity to unrelated tumors and bacterial parasites", J Exp Med. 1977 Feb 1;145(2):275-92
90	C83	Reilly CH, "Microbiology and cancer therapy: A Review", Cancer Res. 13(12): 821
90	C84	Youdim et al., "Resistance to tumor growth mediated by Listeria monocytogenes: collaborative and suppressive macrophage-lymphocyte interactions in vitro", J Immunol. 1976 Nov;117(5 Pt.2):1860-5.
90	C85	Youdim S, "Resistance to tumor growth mediated by Listeria monocytogenes. Destruction of experimental malignant melanoma by LM-activated peritoneal and lymphoid cells", J Immunol. 1976 Mar;116(3):579-84.
9P		Youdim S, et al., "Nonspecific suppression of tumor growth by an immune reaction to Listeria monocytogenes", J Natl Cancer Inst. 1974 Jan;52(1):193-8
90	C87	Youdim.et al., "Cooperation of immune lymphoid and reticuloendothelial cells during Listeria monocytogenes-mediated tumor immunity", Cancer Res. 1977 Apr;37(4):991-6
90	C88	Zinkemagel RM, "Early appearance of sensitized lymphocytes in mice infected with Listeria monocytogenes", J Immunol. 1974 Feb;112(2):496-501
AP)	C89	Experimental Medicine, Vol 12, No. 15, (Supplementary) (1994) p. 1915-1919 (Ref. No. 8 of Japanese Office Action).
9P	C90	Translation of Japanese Office Action mailed February 15, 2002 in connection with Japanese counterpart of U.S. application no. 08/658,034, now U.S. Patent No. 6,190,657, to which the present application claims priority.
EXAMINER		enni Juni Date considered 7/29/2005
		Court - Court

*EXAMINER: Include copy of this form with next communication to applicant.